ORDER FOR SUPPLIES OR SERVICES

PAGE 1 OF PAGES 39

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: 05/24/2019	2. CONTRACT NO. (If any): 68HERH19D0022
3. ORDER NO.: 68HERH19F0199	4. REQUISITION/REFERENCE NO.: PR-OCSPP-19-00290

5. ISSUING OFFICE (Address correspondence to):
HQAD
US Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 3803R
Washington DC 20460

6. SHIP TO:
a. NAME OF CONSIGNEE: HQAD
b. STREET ADDRESS: US Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 3803R
c. CITY: Washington | d. STATE: DC | e. ZIP CODE: 20460

7. TO: David Sprague
a. NAME OF CONTRACTOR: SRC, INC.
b. COMPANY NAME:
c. STREET ADDRESS: 7502 ROUND POND ROAD
d. CITY: NORTH SYRACUSE | e. STATE: NY | f. ZIP CODE: 132122558

f. SHIP VIA:

8. TYPE OF ORDER
☐ a. PURCHASE
REFERENCE YOUR:
Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.

☒ b. DELIVERY
Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA: See Schedule

10. REQUISITIONING OFFICE:

11. BUSINESS CLASSIFICATION (Check appropriate box(es))
☐ a. SMALL ☒ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone
☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB

12. F.O.B. POINT:

13. PLACE OF		14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
a. INSPECTION: Destination	b. ACCEPTANCE: Destination			

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: 063053771 ----- Chemical Screening Review and/or Evaluation of New, Existing and Safer Choice Chemical Substances (CESSD) Human Health Hazard Support for New Continued ...					

SEE BILLING INSTRUCTIONS ON REVERSE

18. SHIPPING POINT	19. GROSS SHIPPING WEIGHT	20. INVOICE NO.	17(h) TOTAL (Cont. pages)
			$225,000.00

21. MAIL INVOICE TO:
a. NAME: RTP Finance Center
b. STREET ADDRESS (or P.O. Box): US Environmental Protection Agency
RTP-Finance Center (AA216-01)
109 TW Alexander Drive
www2.epa.gov/financial/contracts
c. CITY: Durham | d. STATE: NC | e. ZIP CODE: 27711

17(i) GRAND TOTAL: $9,965,543.32

22. UNITED STATES OF AMERICA BY (Signature): 05/24/2019 ELECTRONIC SIGNATURE

23. NAME (Typed): Sheila Dolan
TITLE: CONTRACTING/ORDERING OFFICER

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
05/24/2019	68HERH19D0022	68HERH19F0199

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Chemicals Program(Formerly Task Order 08) ----- Contract COR: Bryan Lobar, lobar.bryan@epa.gov TOCOR: Clifton Townsend, townsend.clifton@epa.gov ----- TOCOR: Clifton Townsend Max Expire Date: 05/23/2024 Admin Office: HQAD US Environmental Protection Agency William Jefferson Clinton Building 1200 Pennsylvania Avenue, N. W. Mail Code: 3803R Washington DC 20460 Period of Performance: 05/24/2019 to 05/23/2020					
0001	Human Health Support for New Chemicals Period of Performance: 05/24/2019 - 05/23/2020 NTE Hours: 16,203 NTE Price: $1,918,219.69 Accounting Info: 18-19-B-69A-000CD6-2505-QT5PSMZZ-TC5PQ QH-1969AC9020-001 BFY: 18 EFY: 19 Fund: B Budget Org: 69A Program (PRC): 000CD6 Budget (BOC): 2505 Job #: QT5PSMZZ Cost: TC5PQQH DCN - Line ID: 1969AC9020-001 Funding Flag: Partial Funded: $150,000.00 Accounting Info: 19-20-B-69A-000CD6-2505-TC5PQQF-1969AC 9020-002 BFY: 19 EFY: 20 Fund: B Budget Org: 69A Program (PRC): 000CD6 Budget (BOC): 2505 Job #: QT5PSMZZ Cost: TC5PQQF DCN - Line ID: 1969AC9020-002 Funding Flag: Partial Funded: $75,000.00				225,000.00	
0002	Human Health Support for New Chemicals Period of Performance: 05/24/2020 - Continued ...				Option	

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) $225,000.00

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
05/24/2019	68HERH19D0022	68HERH19F0199

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	05/23/2021 NTE Hours: 16,203 NTE Price: $1,956,594.38 (Option Line Item) 04/24/2021					
0003	Human Health Support for New Chemicals Period of Performance: 05/24/2021 - 05/23/2022 NTE Hours: 16,203 NTE Price: $1,995,766.75 (Option Line Item) 04/24/2021				Option	
0004	Human Health Support for New Chemicals Period of Performance: 05/24/2022 - 05/23/2023 NTE Hours: 16,203 NTE Price: $2,035,709.24 (Option Line Item) 04/24/2022				Option	
0005	Human Health Support for New Chemicals Period of Performance: 05/24/2023 - 05/23/2024 NTE Hours: 16,203 NTE Price: $2,059,253.26 (Option Line Item) 04/24/2023				Option	
	The obligated amount of award: $225,000.00. The total for this award is shown in box 17(i).					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H)) $0.00

ENVIRONMENTAL PROTECTION AGENCY

Human Health Hazard Support for New Chemicals

CONTRACT: 68HERH19D0022

TASK ORDER NUMBER: 68HERH19F0199

PROJECT TITLE: Human Health Hazard Support for New Chemicals

Task Order Contracting Officer's Representative	**Alternate Task Order Contracting Officer's Representative**
Clifton Townsend USEPA/OCSPP/OPPT/RAD 1200 Pennsylvania Avenue, NW Mail Code 4607M Washington, DC 20460 Phone: (202) 564-1576 Townsend.Clifton@epa.gov	Kara Koehrn USEPA/OCSPP/OPPT/RAD 1200 Pennsylvania Avenue, NW Mail Code 7410M Washington, DC 20460 Phone: (202) 566-0310 Koehrn.Kara@epa.gov

A. Performance Work Statement (PWS)

A1. Background and Purpose

Background

The Risk Assessment Division (RAD) of the USEPA Office of Pollution Prevention and Toxics (OPPT) is responsible for health and environmental hazard/risk assessment of chemicals regulated under The Frank R. Lautenberg Chemical Safety for the 21st Century Act which amends the Toxic Substance Control Act (TSCA) https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act.

This task order supports implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Since the inception of the New Chemicals Review Program under the Toxic Substances Control Act (TSCA) in 1979, OPPT has received over 42,000 premanufacture notices (PMN). PMNs must include data specified in 40 CFR Part 720 and on the PMN form regarding chemical identity, impurities, synonyms/trade names, byproducts, production volume ("PV"), uses, and site information including identity, process descriptions, worker exposure information, information on release to the environment, including the quantity and media of release and control technology used. 40 CFR § 720.50 requires submission of test data in the possession or control of the submitter, parent company, or affiliates, which are related to the effects on human health or the environment. Other data concerning the human health and environmental effects of the new chemical substance that are known to, or reasonably ascertainable by, the submitter must also be described by the submitter as part of the PMN.

The data and information submitted with the PMN submissions undergo a review process. RAD is responsible for conducting a risk assessment to determine whether the new chemical substance presents an unreasonable risk of injury to human health or the environment. As part of developing the risk assessment, RAD evaluates the data and information submitted with the PMN submission (e.g., test data) as well as uses predictive methods (e.g., expert systems, in silico methods, analog analysis, read

across, quantitative structure activity relationships (QSARs)) to estimate the risks of the new chemical substance. The latter is conducted in response to the data-poor situation encountered with many PMNs submitted to the agency. Each PMN has a 90-day regulatory review period, including the risk determination. Technical review must occur in a timely fashion for EPA to complete the regulatory process.

Purpose

The primary purpose of this task order is to assist with the technical review, including but not limited to, the extraction, summary, and use of environmental hazard data to support the risk determination for new chemicals. RAD also regularly develops and updates the predictive methods and pertinent databases to support decision making under TSCA. This task also supports the development and update of predictive methods that support the estimation of environmental hazard and/or risks of new chemicals. Specifically, contractor will support the following activities:

1) Extract all environmental hazard information submitted with new chemical notices and input the information into appropriate databases;
2) Extract all environmental hazard information submitted after the initial review process as directed and input the information into the appropriate databases;
3) Conduct a scientific review of the environmental hazard information to determine the quality, completeness and suitability of the data/information, as directed;
4) Provide a written review of the toxicological information as directed;
5) Maintain and resolve any technical problems with the health databases as they arise; and
6) Use of the captured information for tool update and development when directed.

The Contractor will also develop other technical products from the submitted data/information or those already in EPA's internal database. Examples of these other activities include, but are not limited to, hazard assessments, generation of model inputs and outputs (where appropriate), model maintenance, Quality Assurance and/or Quality Control project plans and/or of other technical work products within the scope of Task Order 8. The details will be explained in Task order 8.

A2. Scope of Work

The purpose of this procurement is to provide support for hazard assessment of new chemicals.

The contractor will be required to have the ability to work on-site in the CBIC or other CBI secured spaces in an EPA building. The contractor may also be given tasks that can be performed remotely and would need to have CBI secured space for those activities. The contractor will have access to CBI machines for the performance of new chemical reviews. The contractor shall supply the necessary resources required for the performance of non-CBI tasks (database searching). The scientific quality of assessments, reports, models, statistical programs and software, and their timely preparation in accordance with new chemical program schedules, are of paramount importance in the performance of this contract.

The contractor shall have the necessary technical and scientific expertise, knowledge and experience to successfully perform all of the tasks identified below. In addition, the contractor shall have a quality assurance/quality control program that maintains the quality of products, as well as an ongoing training program. This is intended to ensure that the contract staff produces quality products, and feedback from OPPT on needed improvements is communicated to the contractor's staff. The contractor shall maintain

and make available upon request complete documentation of QA/QC practices and procedures.

Performance of work under this contract shall be initiated by task orders issued by the Contracting Officer and will encompass tasks in following areas discussed below in Section C.3 (TASKS).

The contractor may receive EPA laptops to facilitate completion of tasks in this task order at the discretion of the CO and TOCORs.

B. TASKS

TASK 1: Project Management and QAPP requirements

Project Management

The Contractor shall provide a Project Manager. The Contractor Project Manager shall report on all aspects of the objectives and progress of this contract to the designated EPA Contracting Officer (CO) and Task Order Contracting Officer Representative (TOCOR) via email, through monthly reports. The Contractor Project Manager also plans, conducts and supervises Task Order (TO) projects, necessitating advanced knowledge and the ability to originate and apply new and unique methods and procedures. The Contractor Project Manager provides advice and counsel to other professionals. The Contractor Project Manager shall notify via email the relevant EPA TOCOR/Alternate TOCOR of any significant difficulties in accomplishing the task listed in the TOs.

In cases where performance objectives and minimum Acceptable Quality Levels (AQLs) are not being met, the Contractor Project Manager will make every effort to immediately correct the problems to ensure customer satisfaction. If the problem persists, the Project Manager will submit a plan of corrective action to the TOCOR and the Contract Level COR. The Contractor Project Manager shall ensure that the approved Quality Assurance (QA)/Quality Control (QC) process is followed to ensure the quality of its products.

QAPP Requirements

Quality Assurance: The Quality Management Plan, the QAPP for Tasks 2 through 5. The contractor shall adhere to its Quality Management Plan that is tailored for this contract.

This Task Order involves the use of existing data. Accordingly, EPA policy requires that an approved Quality Assurance Project Plan (QAPP) be in place before any work begins that involves the collection, generation, evaluation, analysis or use of environmental data. The QAPP must be consistent with EPA Requirements for Quality Assurance Project Plans: EPA QA/R-5 (https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf).

* The contractor shall prepare and submit for EPA review a draft Quality Assurance Project Plan (QAPP) for Tasks 2 through 5 within 10 days of selection and before **the initiation of the rest of the task order**. Updates to QAPP based on comments from the EPA to the QAPP must be received within 3 working days.

* EPA will review the contractor's draft QAPP and provide the Contractor with written approval or written comments.

* If needed, the Contractor shall submit a revised QAPP within 5 business days of receipt of the written comments on the draft QAPP, unless otherwise instructed by the EPA TOCOR. An acceptable QAPP must be received before the rest of the task order is initiated (tasks 2-5), no funds may be received for the following tasks until the contractor's QAPP has been approved.

* Under no circumstances shall work that involves the generation, collection, evaluation, analysis, or use of environmental data be performed by the contractor until the contractor receives written notification from the EPA TOCOR that EPA has approved the contractor's QAPP.

All QA documentation, including the QAPP, prepared under this TO, shall be considered non-proprietary, and shall be made available to the public upon request.

Additional QA Documentation Required

In addition to the requirements described above, all major deliverables (e.g., Technical Support Documents, Study Reports, Study Plans, etc.) produced by the Contractor under this Task Order must include a discussion of the QA/QC activities that were or will be performed to support the deliverable. The contractor shall immediately notify the EPA TOCOR of any QA problems encountered that may impact the performance of this Task Order, with recommendations for corrective action.

The contractor also shall provide EPA with monthly reports of QA-related activities performed during implementation of this Task Order. These monthly QA reports shall identify QA activities performed to support implementation of this task order, problems encountered, deviations from the QAPP, and corrective actions taken. The contractor may include this as a part of the contract-required monthly financial/technical progress report. The contractor shall notify the EPA TOCOR at any time during the task order if changes to the QAPP are warranted (e.g., due to organizational changes, revised technical approaches).

If, during the Period of Performance of this Task Order, the EPA TOCOR determines revisions to the QAPP are necessary, the contractor shall submit a revised QAPP, including the revision summary, within 5 business days after receiving written technical direction to do so. EPA will review the draft revised QAPP and provide the contractor with written approval or comments. The contractor shall provide a revised QAPP, then a final QAPP that responds to EPA's written comments within 5 business days of receipt of EPA's comments on the draft QAPP.

TASK 2. Reporting Requirements

The contractor shall write and submit monthly progress reports to the EPA Task Order Contracting Officer Representative (TOCOR). Progress reports shall describe completed work during the invoice period and should link to charges described in invoice documentation.

Routine progress reports shall include a written monthly technical progress report that includes the following in the case of each project that the contractor is involved in during the month: (a) an overview of work accomplished since project inception to to-date (b) a description of work accomplished during

the month, (c) a summary of QA/QC activities since project inception including a summary of corrective action taken (d) a brief summary of anticipated work during the following month, (e) a summary and details of the LOE and costs incurred **for each task** during the month and cumulatively , and (f) total remaining budget. This report shall also be issued to the Contract Level COR. Routine progress reports shall be delivered electronically; paper copies are not needed.

The Contractor shall notify the TOCOR and CO when 75, 90, and 100% of approved hours have been expended. No work on the conduct of environmental data operations can begin until EPA approval of the QAPP is obtained. Work not related to environmental hazard data operations such as scoping how environmental data may be searched for or summarized once available including refinement of keywords, criteria, or report templates may begin prior to QAPP approval.

Failure to submit monthly progress reports with the information required will result in the suspension of the invoice until such supporting documentation is provided. Any deviations from the project such as work schedules, impediments encountered, and budget require approval from the EPA CO. The EPA CO may also initiate verbal communications with the contractor on an as needed basis to determine project status.

Deliverable: Monthly Progress Reports shall be submitted to the EPA TOCOR within three (3) calendar days of invoice submission to EPA. Minimal level of effort required for this deliverable.

TASK 3: Review of PMNs

The contractor shall support exposure assessors in meeting the objectives of this task order and its responsibilities under TSCA Section 5 by performing the following:

3.1. Extraction of data related to assessment of Human Health effects

The contractor shall provide technical support for EPA's New Chemicals Program by monitoring incoming PMNs and note the availability of data in the calendars. These data shall be abstracted and entered into the PMNBTI database from which data extraction sheets will be made available for use by the SAT. The Contractor shall also summarize the toxicological data identified in the PMNs for review by the SAT experts in the summary formats outlined by the TOCOR and used in the PMN BTI tables and the summary documents.

3.2. Extraction of data (post review process)

The contractor shall extract and summarize all toxicological information received after initial review as directed by the TOCOR. The data shall be entered into either the 5(e)health database or? as required. All toxicological data should be calculated for 100% active ingredient (100%AI) if possible, or state that %AI cannot be determined. The contractor shall also summarize the toxicological data in formats outlined by the TOCOR to evaluate whether the study meets the relevant criteria for rigor and adequacy, as described in the OPPTS Harmonized Test Guidelines, found at:

i. Health Effects:
http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm

The contractor shall make a copy of each new chemical report on media designated for CBI (Confidential Business Information) documents. The contractor shall complete new chemical reports using templates, software, and/or guidance provided by the EPA TOCOR, as described in the approved Quality Assurance Project Plan (QAPP). Changes to this direction will be provided by the EPA TOCOR in written technical direction. The contractor shall maintain copies of all work documentation to include templates, assumptions, raw data, calculation, and information used or produced during the course of this subtask.

The contractor shall have sufficient trained staff to ensure that a trained assessor is available to work every day that reports need to be generated. The contractor should describe staffing and training methods to ensure continuity in the ability to perform hazard assessments.

3.2.1 Create folders in CBI LAN in lieu of Outlook Calendar Preparation

SRC is directed to collect additional information on "same-as" and analog cases and place it in the new Same-as & Analog Data subfolder within the CRSS/SAT folder for the relevant case. SRC is directed to also search the ECHA database to see if data on the case chemical has been submitted. The new folder shall include, when applicable:

1. Available SAT reports for "same-as" and analog cases
2. Copy of Data extractions and/or summary sheets (PMBTI and/or 5e) for same-as and analog cases

Please also list all "same-as" and analog data/studies that have been previously extracted by SRC in summary sheet for PMN (see Sample Summary Coversheet), and label it as such when saving to folder.

SRC is directed to search for potential analogs of the case chemical and analog data by searching frequently used databases. SRC is directed to provide a list of the potential analogs and available data in the summary table. More information about analog searching is provided under 3.3 below.

3.2.2 SRC will create in each PMN's <u>CRSS-SAT</u> folder:

- Submitted Documents and Data
- Contractor Extractions
- **Same-as & Analog Data Folder containing the following:**
  - Same as SAT Reports, 8es, and Study/Data Extractions
  - Table of Analogs, the source of analogs, and type of data (eg. ECHA, SIDS, HPV, 8e) (see 3.3 below) Do not list individual studies.
- The summary sheet will list "Same-as" cases and or analogs and any identified human health documents or data sources.

<u>3.2.3 Extractions of submitted data and Flagged items</u>

Items submitted should be entered into summary coversheet in order of relevance to the PMN – begin list with PMN specific studies, followed by analog data, submitted reports, other documents, etc. Note any flagged items in the Status column of the coversheet as shown in Appendix A. The coversheet does not need to be uploaded until the data review/extraction is completed but SRC may make a "DRAFT" version available if a large number of studies have been submitted and they won't all be available at the same time.

Do not extract ECHA data, SIDS reports, secondary reports (e.g., HERA studies) or publicly available information extracted but do want it listed in the coversheet and placed in the PMN's folder as outlined above. Any information submitted that is unclear and cannot be readily extracted but appears to be of value should be extracted (if possible) and flagged; and the TOCOR, alt-TOCOR and HH assessor should be notified ASAP of the specific issue encountered.

Reasons to flag submitted data (examples):

1) Can't discern the tested substance (email and note in the database)
2) Data summaries provided without full studies (email and note in database)
3) Analog data cited without reference (email)
4) Study summaries only – potentially incomplete (email ASAP)
5) Source unknown (note in database)
6) Something looks unusual (email and note in database)

3.3 Identifying Analogs and Data

The contractor shall identify analogs and search for analog data in frequently used databases (listed below) and provide information on whether data exists in these sources but will not retrieve the data. Analog searches will be conducted based on the structure of the submitted chemical and any "structurally related" substances identified by contractor chemists. Good analogs will have shared functionalities, and structural commonality should focus on the most reactive sites of the molecule which often drive hazards. The sources used to search for analogs should include the following resources only, in the order listed, unless instructed otherwise by the EPA TOCOR. The overall search strategy will be left up to the contractors preparing the cases. Contactor should spend less than 30 minutes searching for human health analogs and available analog data in the following databases (does not include chemist ID of analogs). Structural alerts, chemical category, and submitted data should be done by CRSS (as currently done) and analog searches (below) should be done by COB the day of CRSS.

3.3.1 Search for human health analogs:

1. Identify structural alerts and potential chemical categories – this can be accomplished before CRSS in concert with chemistry and ecotox analogs; EPA will supply a list of structural alerts and update the list periodically; categories should be from the EPA NCP 2010 document.
2. Analog Identification Methodology (AIM) – CBI Version
3. CHEMIDPlus

3.3.2 Search for data on human health analogs:

1. Current data used by EPA Health Assessors
2. AIM- CBI Version
3. ChemView (EPA HPV Program documents, 8e)
4. ECHA
5. OECD SIDS

3.4 Review of all repeated dose studies submitted with initial submission

SRC is tasked with reviewing all repeated dose studies submitted with initial submission without requiring direction from the TOCOR to do so. SRC will be given 3 weeks from day of CRSS to review and extract all information present in those repeated dose studies. Upon identification of all repeated dose studies submitted for cases going to CRSS, SRC will notify the TOCOR and the HH assessor responsible for that list. If any problems are discovered with the study SRC will inform the HH assessor and TOCOR too.

3.5 Inform Human Health Assessor of saved studies and extracted summaries

SRC staff should inform the human health assessor assigned to the specific case when documents and extractions have been placed in the PMN's folder. EPA request that all submitted studies and supporting documents are uploaded in bulk to the case folder right away, and notifications be sent when finished with extractions or at your discretion (based on number of studies) as needed (the coversheet does not need to be uploaded until the data review/extraction is completed but flagged items that need follow up should be sent right away). Please cc TOCOR and alt-TOCOR in your message.

3.5.1 Example of a summary coversheet

The summary coversheet should contain a list of all submitted studies/analyses and uncovered "same-as" or appropriate analog data and they shall be identified by type and title (columns: Document and Type/Title). SRC should note if the study/summary/report pertains to the PMN, "same-as" or an analog (column: Substance). SRC should include the status, if applicable (Column: Status).

Note that it is acceptable to leave the Substance or Status column blank. See on Sample Summary Coversheet

Sample Summary Coversheet

Title: L-18-XXXX Summary Coversheet

Document/Guidance number (if applicable)	Study Type and Title*	Substance	Status
OECD 422	Combined Repeated Dose, Developmental/Reproductive Toxicity Study	PMN or Same-As or Analog	Extracted
Other Data	May just be a list of NOAELs/LOAELs or other endpoints with no study information	PMN or Analog or unknown	Not Extracted - Mix of analog, PMN data, studies/references not provided – inform alt-TOCOR right away (cc TOCOR)
Sustainable Futures Report		PMN, Same-As, and/or Analog	Saved
Risk assessment Report		PMN, Same-As, and/or Analog	Saved
AIM		Same-As, and/or Analog	List of potential analogs
ChemView		Same-As, and/or Analog	List of potential analogs
ChemIDPlus		Same-As, and/or Analog	List
ECHA		Same-As, and/or Analog	Data available
OECD SIDS		Analog	Data available available, year of publication
EPA HPV Hazard Characterization		Analog	Data available and link if available
8(e) data		Same-As, and/or Analog	Data available and link if available

*Items submitted to be entered in order of relevance to the PMN – begin list with PMN specific studies, followed by analog data, other documents, etc. Note any flagged items in the Status column.

3.6 Data Extraction

The contractor shall obtain all TSCA-related information for a list of chemicals provided by EPA. The contractor shall also do the following: Obtain information for the development of EPA toxicity values of chemical listed by EPA (ex. PFAS). Note that some information may already be gathered, and some information is associated with specific PMNs so the searches may differ slightly by chemical.

3.6.1 Support EPA Toxicity Values

3.3.1 a Determine Literature availability

EPA is developing toxicity values for chemicals. EPA is ideally interested in all available chemical data available. This includes animal toxicity studies/data, human epidemiological data, ecotoxicity studies, biomonitoring data, physical-chemical properties and environmental fate information. Please provide a matrix of the number of "hits" for these chemicals.

3.6.1 b Duplicate removal and obtain data

Based in the results of the matrix (Subtask a), EPA and SRC can then determine whether to obtain all pdfs or a subset of pdfs. When combining the results of multiple databases, SRC should remove duplicates as appropriate.

3.6.1 c Develop inclusion/exclusion criteria to screen studies

The contractor shall propose inclusion/exclusion criteria to exclude non-relevant studies or submissions that include only short abstracts.

3.6.1 d Organize data

Pdfs should be organized in a Task 1 folder on the CBI LAN and separated into non-CBI and CBI subfolders. EPA can work with SRC to identify which studies are not CBI. Data should further be organized by discipline (e.g., physical-chemical properties, environmental fate, human health toxicity, ecotoxicity, biomonitoring data, occupational monitoring data, environmental media/wildlife monitoring data).

3.6.1 e Document search and screening process to obtain relevant information

SRC should provide a very brief literature flow chart. This should include numbers of studies identified for the different sources of data (CIS, ChemView, etc.), number of studies after duplicate removal, number of studies excluded (and reasons for exclusions). In addition, SRC should provide a brief narrative of the process used to do searches.

Table 1. Deliverable Schedule

Meeting or Task	Target Due Date	Comments
Kickoff meeting	3 days after receiving the TD	An estimate of LOE to complete the TD should be presented at the meeting
Task 1, Subtask a	3 days after kickoff meeting	
Task 1, Subtask b	3 weeks after kickoff meeting	
Task 1, Subtask c	~ 1 week after kickoff meeting	
Task 1, Subtask d	TBD	
Task 1, Subtask e	TBD	

Table 2. Chemicals and Searches to Conduct

This table lists the CASRNs and chemical names and synonyms (only if needed – the full list may not be necessary) for the Task 1 chemicals. This table identifies whether the information is required for Tasks 1. The contractor can expect that this chemical list will be updated by EPA to conduct additional chemical searches.

CASRN	Chemical Synonyms	Notes on Requested Searching
375-22-4 [pfba]	2,2,3,3,4,4,4-Heptafluorobutanoic acid 4-02-00-00810 Acide heptafluorobutyrique BRN 1426882 Butanoic acid, 2,2,3,3,4,4,4-heptafluoro- Butanoic acid, heptafluoro- Butyric acid, heptafluoro- EC 206-786-3 EINECS 206-786-3 Fluorad FC 23 Heptafluorbuttersaure Heptafluoro-1-butanoic acid Heptafluorobutanoic acid Heptafluorobutyric acid Kyselina heptafluormaselna NSC 820 PFBA Perfluoro-n-butanoic acid Perfluorobutanoate Perfluorobutanoic acid Perfluorobutyric acid Perfluoropropanecarboxylic acid acido heptafluorobutirico heptafluorobutyric acid	Tasks 1[a] and 2 Search full set of data sources; some studies may have come in under Section 5 but there is no list of PMNs to search.
10495-86-0 [pfba ammonium salt]	Ammonium Perfluorobutanoate Butanoic acid, 2,2,3,3,4,4,4-heptafluoro-, ammonium salt (1:1) PFBA-H3N	
2218-54-4	Butanoic acid, 2,2,3,3,4,4,4-heptafluoro-, sodium salt (1:1)	

CASRN	Chemical Synonyms	Notes on Requested Searching
[pfba sodium salt]	Butanoic acid, heptafluoro-, sodium salt Heptafluorobutanoic acid, sodium salt PFBA-Na Sodium Perfluorobutanoate Sodium heptafluorobutyrate Sodium perfluorobutanoate	
3794-64-7 [pfba silver salt]	Butanoic acid, 2,2,3,3,4,4,4-heptafluoro-, silver(1+) salt (1:1) Butanoic acid, heptafluoro-, silver(1+) salt PFBA-Ag Silver Perfluorobutanoate Silver heptafluorobutyrate Silver perfluorobutanoate	
45048-62-2 [pfba ion]	PFBA_ion Perfluorobutanoate	
307-24-4 [pfhxa]	2,2,3,3,4,4,5,5,6,6,6-Undecafluorohexanoic acid EINECS 206-196-6 Hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro- Hexanoic acid, undecafluoro- NSC 5213 PERFLUOROHEXANOIC ACID PFHxA Perfluoro-1-pentanecarboxylic acid Perfluoro-n-hexanoic acid Perfluorohexanoate Perfluorohexanoic acid UNII-ZP34Q2220R Undecafluoro-1-hexanoic acid Undecafluorocaproic acid Undecafluorohexanoic acid	Task 1 [a] Studies submitted under Section 5 are in the following CBI folder: G:/RAD-Kelly Mayo/ Kmayo (WAS-FS-etc)/RAD C6 Studies and Reviews/ Please gather and review these first. Then, please also check CIS, CBIC (for physical copies) and J:/POSTFOCUS/… for any PFHXA (or PFXHA salt) studies not in the above folder that may have been submitted with the PMNs identified in the CBI version of this TD [at J:/SRC/PFAS Data Searches]. The relevant J:/POSTFOCUS folders for the identified PMNs that may contain
2923-26-4 [pfhxa sodium salt]	Hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-, sodium salt (1:1) Hexanoic acid, undecafluoro-, sodium salt PFHxA-Na Sodium Perfluorohexanoate	

CASRN	Chemical Synonyms	Notes on Requested Searching
	Sodium perfluorohexanoate Sodium undecafluorohexanoate Undecafluorohexanoic acid, sodium salt	information in addition to CIS, other sources, are J:/Postfocus/FY2005 FY2006 FY2007 FY2008 FY2009 FY2010 Within these folders are subfolders for PMNs submitted during these years. Then search full set of data sources.
21615-47-4 [pfhxa – ammonium salt]	Ammonium Perfluorohexanoate Ammonium perfluorohexanoate Hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-, ammonium salt (1:1) Hexanoic acid, undecafluoro-, ammonium salt PFHxA-H3N Undecafluorohexanoic acid, ammonium salt	
92612-52-7 [pfhxa ion]	PFHxA_ion Perfluorohexanoate	
355-46-4 [pfhxs]	1,1,2,2,3,3,4,4,5,5,6,6,6-Tridecafluoro-1-hexanesulfonic acid 1,1,2,2,3,3,4,4,5,5,6,6,6-Tridecafluorohexane-1-sulfonic acid 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro- 1-Hexanesulfonic acid, tridecafluoro- 1-Perfluorohexanesulfonic acid EC 206-587-1 EINECS 206-587-1 PFHS PFHxS Perfluorhexan-1-sulfonsaure Perfluoro-1-hexanesulfonate Perfluorohexane sulfonic acid (PFHxS) Perfluorohexane-1-sulphonic acid Perfluorohexanesulfonate Perfluorohexanesulfonic acid Perfluorohexylsulfonate Tridecafluorohexanesulfonic acid acide perfluorohexane-1-sulfonique acido perfluorohexano-1-sulfonico perfluorohexane-1-sulphonic acid	Task 1 [a] Search full set of data sources.

CASRN	Chemical Synonyms	Notes on Requested Searching
	perfluorohexanesulfonic acid	
68259-08-5 [pfhxs ammonium salt]	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ammonium salt (1:1) Ammonium Perfluorohexanesulfonate Ammonium perfluorohexanesulfonate PFHxS-H3N Tridecafluoro-1-hexanesulfonic acid, ammonium salt	
3871-99-6 [pfhxs potassium salt]	1,1,2,2,3,3,4,4,5,5,6,6,6-Tridecafluorohexane-1-sulfonic acid, potassium salt 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, potassium salt 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, potassium salt (1:1) PFHxS-K Potassium Perfluorohexanesulfonate Potassium perfluorohexanesulfonate	
55120-77-9 [pfhxs lithium salt]	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, lithium salt 1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, lithium salt (1:1) Lithium Perfluorohexanesulfonate Lithium perfluorohexanesulfonate PFHxS-Li	
108427-53-8 [pfhxs ion]	1-Hexanesulfonic acid, 1,1,2,2,3,3,4,4,5,5,6,6,6-tridecafluoro-, ion(1-) PFHxS ion(1-) PFHxS_ion Perfluorohexanesulfonate Tridecafluorohexane-1-sulfonate perfluorohexyl sulfonate	
647-42-7 [c6 alcohol]	1,1,2,2-Tetrahydroperfluoro-1-octanol 1,1,2,2-Tetrahydroperfluorooctan-1-ol 1,1,2,2-Tetrahydroperfluorooctanol 1,1,2,2-Tetrahydrotridecafluorooctanol 1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro- 1H,1H,2H,2H-Perfluoro-1-octanol 1H,1H,2H,2H-Perfluorooctan-1-ol	Search full set of data sources.

CASRN	Chemical Synonyms	Notes on Requested Searching
	1H,1H,2H,2H-Perfluorooctanol 1H,1H,2H,2H-Tetrahydroperfluoro-1-octanol 1H,1H,2H,2H-Tridecafluoro-1-octanol 1H,1H,2H,2H-Tridecafluoro-n-octanol 1H,1H,2H,2H-Tridecafluorooctanol 2-(Perfluorohexyl)ethanol 2-(Perfluorohexyl)ethyl alcohol 2-(Tridecafluorohexyl)ethanol 3,3,4,4,5,5,6,6,7,7,8,8,8-Tridecafluoroctan-1-ol 3,3,4,4,5,5,6,6,7,7,8,8,8-Tridecafluorooctan-1-ol 3,3,4,4,5,5,6,6,7,7,8,8,8-Tridecafluorooctanol 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctane-1-ol 6:2 FTOH 6:2 Fluorotelomer alcohol Capstone 62AL Cheminox FA 6 EINECS 211-477-1 Fluorotelomer alcohol 6:2 Fluowet EA 600 Foralkyl EOH 6 FtOH 6:2 Perfluorohexylethanol TEOH 6 UNII-G2R5YO5N3V 1,1,2,2-Tetrahydroperfluoro-1-octanol 1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro- 1H,1H,2H,2H-Perfluorooctanol Fluorotelomer alcohol 6:2 FtOH 6:2	
375-95-1 [pfna]	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-Heptadecafluorononanoic acid C 1800 EINECS 206-801-3 Heptadecafluornonansaeure	Task 1 [a] Search full set of data sources.

CASRN	Chemical Synonyms	Notes on Requested Searching
	Heptadecafluorononanoic acid Heptadekafluornonansaeure Nonanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,9-heptadecafluoro- Nonanoic acid, heptadecafluoro- PERFLUORONONANOIC ACID PFNA Perfluornonansaeure Perfluoro-n-nonanoic acid Perfluorononanoate Perfluorononanoic acid Perfluorononanoic acid (PFNA) Perfluorononanonic acid Perfluoropelargonic acid UNII-5830Z6S63M perfluoro-n-nonanoic acid perfluorononan-1-oic acid perfluorononanoic acid	
15899-31-7 [pfna isononoanoic acid]	Methyl-n1-Perfluorononanoic acid Octanoic acid, 2,2,3,3,4,4,5,5,6,6,7,8,8,8-tetradecafluoro-7-(trifluoromethyl)- Octanoic acid, tetradecafluoro-7-(trifluoromethyl)- PFNA-n1CH3 Tetradecafluoro-7-(trifluoromethyl)octanoic acid	
4149-60-4 [pfna ammonium salt]	Ammonium Perfluorononanoate Ammonium perfluorononanoate Nonanoic acid, heptadecafluoro-, ammonium salt PFNA-H3N	
72007-68-2 [pfna ion]	PFNA_ion Perfluorononanoate	
335-76-2 [pfda]	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-Nonadecafluorodecanoic acid 4-02-00-01052 BRN 1810811 Decanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluoro-	Search full set of data sources.

CASRN	Chemical Synonyms	Notes on Requested Searching
	Decanoic acid, nonadecafluoro- EC 206-400-3 EINECS 206-400-3 Ndfda Nonadecafluordecansaeure Nonadecafluoro-n-decanoic acid Nonadecafluorodecanoic acid PFDA Perfluoro-1-nonanecarboxylic acid Perfluoro-n-decanoic acid Perfluorocapric acid Perfluorodecanoate Perfluorodecanoic acid acide nonadecafluorodecanoique acido nonadecafluorodecanoico nonadecafluoro-n-decanoic acid nonadecafluorodecanoic acid perfluoro-n-decanoic acid	
3108-42-7 [pfda ammonium salt]	Ammonium Perfluorodecanoate Ammonium nonadecafluorodecanoate Ammonium perfluorodecanoate Decanoate, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluoro-, ammonium salt (1:1) Decanoic acid, 2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluoro-, ammonium salt (1:1) PFDA-H3N PFDAA	
73829-36-4 [pfda ion]	PFDA_ion Perfluorodecanoate	
958445-44-8 [adona]	3H-Perfluoro-3-[(3-methoxy-propoxy)propanoic acid] ammonium salt ADONA Ammonium 2,2,3-trifluoro-3-[1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy) propoxy]propanoate Ammonium 4,8-dioxa-3H-perfluorononanoate DONA-H3N	Search full set of data sources.

CASRN	Chemical Synonyms	Notes on Requested Searching
	Propanoic acid, 2,2,3-trifluoro-3-[1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy)propoxy]-, ammonium salt Propanoic acid, 2,2,3-trifluoro-3-[1,1,2,2,3,3-hexafluoro-3-(trifluoromethoxy)propoxy]-, ammonium salt (1:1)	
908020-52-0	Acetic acid, 2,2-difluoro-2-[1,1,2,2-tetrafluoro-2-(1,1,2,2,2-pentafluoroethoxy)ethoxy]-, ammonium salt EEA-NH4	Search full set of data sources.
329238-24-6	Fluorolink 7850	Search full set of data sources.
69991-62-4	Fluorolink PT-5071 Ethaene, 1,1,2,2-tetrafluoro-, oxidized, polymd., reduced	Search full set of data sources.

[a] **Note:** this work should not duplicate work done under a previous task through an NCEA contract; therefore, some work will simply be an update to previous searches for public submissions under TSCA 8e, etc.

TASK 4: Support of Predictive model and/or tool development

The Contractor shall also support predictive model and/or tool development through collection, evaluation, and validation of the toxicological data described above to support enhancements to OPPTs predictive models as directed by the TOCOR. This may include: Investigating new QSARs to add to ECOSAR which may include QSARs for new organics classes, polymers, surfactants, dyes, inorganic chemicals, organometallics, perfluorinated elements, and metals; and drafting or revising documentation such as the new QSAR manual sheets to support the new algorithms or approaches.

TASK 5: Supplemental Support on PMN Human Health Hazard Assessment

EPA's Office of Pollution Prevention and Toxics is working on streamlining various aspects of the New Chemicals Program including the work flow related to the development of RAD's technical products. The office has a goal to transition to a LEAN process in calendar year 2019. This task will request additional support from SRC to start preparing for the change.

5.1 Run OECD QSAR toolbox profilers as part of the pre-SAT activities to support the initial human health (HH) hazard characterization of PMN substances

In conjunction with the work performed under Task 3 in support of HH hazard assessments, SRC is tasked with also running OECD QSAR toolbox profiles.

As access to the OECD QSAR toolbox may take several days to grant, SRC should download non-CBI version of the OECD QSAR toolbox located at http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm. The non-CBI tool will allow SRC to familiarize with the sensitization profilers. The website has guidance documents and training materials for the sensitization profilers. EPA will organize a demo to show SRC how to use the sensitization profilers. After familiarizing with the tool box, SRC should collect any questions/issues they may have to facilitate the discussion with HAZRATT members.

5.2 Planning activities to implement future LEAN process affecting PMN HH hazard characterizations

SRC is tasked to schedule meetings with EPA's HAZRATT members (Appendix A) to begin the planning activities for changing the work flow of the PMN HH hazard/risk reports to support LEAN efforts. Below are examples of topics that will be discussed at the initial meeting and future meetings.

- current work flow process and SRC deliverables to support the pre-SAT and pre-FOCUS hazard work
- New work flow process under LEAN (e.g., team approach)
- Opportunities to improve the current QC system of Part A and B forms.
- Opportunities for SRC to help with transition including ideas for work flow improvements based on SRC's experience with supporting human health, eco and fate work for the PMN program.
- Link to the share point document for up-to-date assignments of health assessors: https://usepa.sharepoint.com/:w:/r/sites/OCSPP/OPPT/rad/_layouts/15/Doc.aspx?sourcedoc=%7BAE0FA60F-6C78-4E6F-9FFB-9637094099F1%7D&file=HazRATT-%20SAT%20and%20FOCUS%20Assignments-%20updated%2011.20.18.docx&action=default&mobileredirect=true

5.2.1 Support for SAT meetings

a. SRC will select and send at least one dedicated human health hazard assessor to the pre-SAT meetings. The selected SRC assessor(s) should have expertise in toxicology and/or human health hazard and risk assessment. Experience in the PMN program and analogue identification is preferred. The meetings take place every Monday and Thursday, 3-4 pm. The SRC assessor is expected to learn how to develop Part A assessments (hazard identification) by working closely

with the Part A assessor (see Part A rotation in Appendix B – subsequent schedules will be shared when they become available) and other assessors attending the pre-SAT meeting. During the meeting, the SRC assessor is encouraged to ask clarifying questions and expected to take notes on how EPA assessors do the Part A assessment, and document any questions that will require follow up with the EPA Technical Contact (Iris Camacho), SAT chairs or other EPA HH assessors, as well as document all ideas for improvements (e.g., efficiencies in analogue searches, updates to the POD/endpoint database developed by Ernest Falke, documentation of EPA practices to support SOP development). The SRC assessor is expected to read the Part A SOP prior to the pre-SAT meeting and be aware of the list of PMN cases (CRSS list) going to SAT.

b. If follow-up questions are required to resolve or clarify EPA procedures, then after each meeting, the SRC assessor will send an e-mail with clarifying questions to this TD's Technical Contact (Iris Camacho) and the EPA Part A assessor and Keith Salazar (cc'ing the TOCOR) to ensure support for Part A can commence as quickly as possible.
c. SRC staff is required to attend SAT meetings, and when necessary, play the HH assessor role (fill on for HH assessors when none are available – SRC will be notified at least 2-3 days in advanced when needed) and/or provide presentation support to the assigned assessor for the human health hazards of PMN cases being discussed at the meeting.
d. SRC will assist with the tracking of the QC review of Part As. EPA will provide the format for the Excel spreadsheet to track the status of the QC process. EPA will provide training on where to locate the files to extract the information that will be added to the tracking sheet. Also, SRC will communicate with RAD HH assessors and cc Technical Contact (Iris Camacho) and Keith Salazar to better track the QC process. Examples of communications: emails to find out the status of the QC process, locate missing files, rectify version control issues.

5.2.2 Support for FOCUS meetings

e. SRC will send a human health hazard assessor to the pre-FOCUS meetings. The SRC assessor should have expertise in toxicology and/or human health hazard and risk assessment. Experience in the PMN program is preferred. The meetings take place every Monday and Thursday, 10-11 am. The SRC assessor is expected to learn how to develop Part B assessments (risk estimation) by interacting with the Part B assessor (see Part B rotation on link attached above) and other assessors attending the pre-FOCUS meeting.

   During the meeting, the SRC assessor is expected to ask questions and document how EPA assessors do the Part B assessment and identify any questions that will require follow up with the EPA Technical Contact (Iris Camacho) or other EPA HH assessors, as well as ideas for improvements. The SRC assessor is expected to read the Part B SOP prior to the pre-SAT meeting and be aware of the list of PMN cases (CRSS list) going to SAT.

   i. The SRC assessor will learn how Part B forms are populated and interact with the EPA Part B assessor by shadowing them as soon as the FOCUS list is available, which happens prior to the pre-FOCUS meeting. Once the assigned SRC assessor is identified, EPA and SRC will work the logistics to ensure that the communications are relayed timely, as work is sensitive to current work flow timelines and specific training will be provided to the SRC assessor (e.g., using our PMN calculator spreadsheets).

f. If follow-up or clarifying questions are required to resolve EPA procedure, then after each meeting the SRC assessor will 1. Update the Case Request Spreadsheet located on the CBI LAN J:\New Chem Data Review and/or 2. the send an e-mail with clarifying questions to the TOCOR (Clifton Townsend) and the EPA Part B assessor to ensure support for Part B can commence as quickly as possible. The email will focus on what the SRC assessor has learned, if they have

identified any inconsistencies, and any general questions about the process or analytical work supporting Part B development.

g. SRC staff is required to attend FOCUS meetings, and when necessary, provide presentation support for the human health hazards of PMN cases being discussed at the meeting.
h. SRC will assist with the tracking of the QC review of Part Bs. EPA will provide the format for the Excel spreadsheet to track the status of the QC process. EPA will provide training on where to locate the files to extract the information that will be added to the tracking sheet. Also, SRC will communicate with RAD HH assessors and cc TOCOR (Clifton Townsend) to better track the QC process. Examples of communications: emails to find out the status of the QC process, locate missing files, rectify version control issues. SRC will also add the completed Part Bs into the proper CBI folders containing final FOCUS HH reports and load or verify that final FOCUS HH reports are in NCR.
i. SRC will start developing Part B forms. SRC assessors should communicate with TOCOR (Clifton Townsend) and Keith Salazar, Human Health Assessor lead to discuss assignments and on the job training.

5.3 Support for writing hazard narratives for risk determination documents

1. SRC is tasked with identifying various assessors that will receive training on how to write hazard narratives for risk determination documents.
2. The SRC assessors should have expertise in toxicology and/or human health hazard and risk assessment. Experience in the PMN program is preferred.
3. EPA will provide training to SRC assessors if need be. SRC assessors will be expected to start writing hazard narratives as soon as possible after receiving training (within a week is preferable).
4. SRC will assist in revising the health reports in NCR based on comments received from OPPT reviewers (e.g., comments from OPPT IO reviewers). These edits are necessary to clean documents before finishing risk determination documents and posting documents on the docket. Once the SRC staff revises the human health reports, EPA will review the revisions and post the document in NCR or ask SRC to assist with the posting.

5.4 Support for post-FOCUS human health work

SRC is tasked to assist EPA with a variety of post-FOCUS HH work that may not be already covered. The selected SRC assessor(s) should have expertise in toxicology and/or human health hazard and risk assessment. Experience in the PMN program and analogue identification is preferred. Assignments will be made on a case by case. Example of post-FOCUS work is the following:

1. **After** review of a company's submitted human health hazard information as part of the post-FOCUS process of the PMN program and conduct activities such as:
    a. Writing the draft memo (EPA will provide example memos)
    b. Revising health reports (Part A/B) after an EPA health assessor determines changes to be made based on conclusions in memo.
2. Review company's memo requesting re-analysis of toxicological information including but not limited to animal toxicity tests and alternative test methods and develop summaries and recommendations of how the science issue(s) should be addressed
3. Review the appropriateness of analogues that have been challenged by submitters to support human health hazard characterization including scientific rationale for selection

5.5 Support for evaluation of the suitability of the generic name

Background: When a Notice of Commencement is received by the agency, inventory listing is triggered, and the generic name provided by the submitter is further analyzed to determine its appropriateness for listing. The

statutory text at TSCA section 5(d) states that "notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest" and with reference to the creation of the TSCA Inventory itself at TSCA section 8(b)(2) "the Administrator may, in lieu of listing,… a chemical substance individually, list a category of chemical substances in which such substance is included" for which it is necessary to interpret a health and safety study if "toxicologically significant portions of the molecule," were disclosed.

Description of Task: The contractor shall support the Risk Assessment Division (RAD)'s reviews of generic names, as directed by the TOCOR. The expected expertise is a toxicologist with a strong chemistry background or a chemist with a strong toxicology background. This shall include, (1) following the regulations at 40 CFR 720.90 relating to generic name, (2) reviewing the structure of the PMN substance to note structural features of possible toxicological importance, (3) reviewing the full chemical name and generic name provided by the submitter, and (4) recommending whether or not the submitter's proposed generic name contains enough information identified in (1 above) to adequately interpret toxicological findings, generally for a health and safety study which has been submitted.

5.6 Reviewing and Editing Human Health Risk Assessments for Older Cases (i.e., the Backlog)

a) SRC is tasked with reviewing and editing old PMN cases. The list of cases to be reviewed will be provided on a rolling basis by the EPA TOCOR or the EPA CASE spread sheet located on the CBI LAN J:\ New Chem Data Review SRC will review the human health reports for scientific quality, clarity, and consistency. In a separate email, EPA will provide SRC with examples of recent edited PMNs as well as a step-by-step checklist of required edits. SRC will perform the requested review of the cases in the order of highest priority (if specified) and upon completing each review will notify the TOCOR, as well as updating the case spread sheet.
b) If need be, SRC will update the SAT report in NCR for edits made to the Human Health reports on a continuing basis as requested by EPA.
c) Compile PMN Case Reports as PDFs & Perform Certain 'Checks' For EACH of the following cases, prepare a FOLDER Here: J:\New Chem Data Review\Back Log (High Priority) TH

1. In EACH Folder, compile the following Reports as PDF files, labeled as indicated:

- P-YR-####_CHEM Report
- P-YR-####_ECO Report
- P-YR-####_ENG Report
- P-YR-####_EXP Report
- P-YR-####_FATE Report
- P-YR-####_HLTH Report
- P-YR-####_HLTH Report_POST-FOCUS FINAL
- P-YR-####_SAT Report

2. The Process for compiling is as follows … workflow organized in the order of the list of Reports under the IR tab

In NCR/CRA: navigate to the Case #

a. P-YR-####_CHEM Report

- Under IR Report Tab: select View/Edit Chemistry Report
  - check it is marked "Complete" (middle of screen after **Chemistry Report:**)
    - If not → **STOP** and inform EPA
    - If so, Print (blue button on Right) → say "OK" to landscape message → Print to Adobe PDF

- Name as above and put into Folder P-YR-####

- Once the PDF is created → use the Find tool (magnifying glass) to search the document for the word "test"
  - If "test" is found → **STOP** and inform EPA
  - If "test" is not found, close file and add "_checked" to the file name

b. P-YR-####_FATE Report

- Under IR Report Tab: select View/Edit Fate Report
  - check it is marked "Complete" (middle of screen after **Fate Report:**)
    - If not → inform EPA and **STOP**
    - If so, Print (blue button on Right) → Print to Adobe PDF
  - Name as above and put into Folder P-YR-####
- Once the PDF is created → use the Find tool (magnifying glass) to search the document for the word "test"
  - If "test" is found → **STOP** and inform EPA
  - If "test" is not found, close file and add "_checked" to the file name

c. P-YR-####_HLTH FATE Report

- Under IR Report Tab: select View/Edit Health Report {this is the SAT Health Report in NCR/CRA for cases PRIOR to deployment of the new Health Report}
  - check it is marked "Complete" (middle of screen after **Health Report:**)
    - If not → **STOP** and inform EPA
    - If so, Print (blue button on Right) → Print to Adobe PDF
  - Name as above and put into Folder P-YR-####
- Once the PDF is created → use the Find tool (magnifying glass) to search the document for the word "test"
  - "Test" will be found in the title **"Exposure-Based Testing"**
    - if there is any testing listed after this heading –> **STOP** and inform EPA
    - if there is NO ENTRY after this heading → proceed
  - If "Test" is found in the **Health Summary** in the context of describing test data submitted or test results summary, it is OK → proceed
  - "Test" will be found in the title **"Test Data Submitted"**
    - This is OK → Proceed
  - If "Test" is found in the context of Testing Recommended or Testing Required, etc. → **STOP** and inform EPA
  - If no inappropriate uses of "Test" are found, close file and add "_checked" to the file name

d. P-YR-####_ECO Report

- Under IR Report Tab: select View/Edit Ecoox Report
  - check it is marked "Complete" (middle of screen after **Ecotox Report:**)
    - If not → **STOP** and inform EPA
    - If so, Print (blue button on Right) → Print to Adobe PDF
  - Name as above and put into Folder P-YR-####
- **Check for Testing:** Once the PDF is created → use the Find tool (magnifying glass) to search the document for the word "test"
  - "Test" will be found in the title **"Exposure-Based Testing"**
    - if there is any testing listed after this heading –> **STOP** and inform EPA
    - if there is NO ENTRY after this heading → proceed
  - "Test" will be found in the following headings: **Test organism, Test Type, Test Endpoint**

        - These are OK → proceed
    - "Test" may be found in the text field labeled **Ecotox Value Comments**
        - It 'test' is used in describing test data or testing received, this is OK → Proceed
    - If "Test" is found in the context of Testing Recommended or Testing Required, etc. → **STOP** and inform EPA
- **Check for Hazard Level (high, moderate, low) to Appropriate Values**
    - Near the end of the Ecotox report, there should be "Environmental Hazard:" section under the heading, **Ecotox Factors Comments** heading.
    - There should be a description of the hazard level of the chemical (i.e., high, moderate or low); this description should be based on **Toxicity Values…NOT COCs.**
    - **CORRECT:** "These toxicity values indicate that the new chemical substance is expected to have low/moderate/high environmental hazard" {Note: for NES chemicals the language is different}
    - **INCORRECT:** something like: the COCs indicate the new chemical has low hazard…(i.e., hazard level attributed based on COC…is wrong)
    - **If eco hazard is attributed based on COCs → STOP** and inform EPA
- If no inappropriate uses of "Test" or inappropriate attribution of hazard call to COCs, close file and add "_checked" to the file name

e. P-YR-####_SAT Report

- IF any of the these were found above:
    - "Test" was found in the FATE Report,
    - Inappropriate "Test" was found in the Ecotox Report
    - Hazard level was attributed to COCs in the Ecotox Report
    - **STOP** and inform EPA {the FATE and/or Ecotox Reports must be updated and then the SAT Report Updated before the SAT Report can be printed and checked.
- IF none of the above were found,
    - check it is marked "Complete" (middle of screen after **SAT Report:**)
        - If not → inform EPA and **STOP**
        - If so, Print (blue button on Right) → PDF Print → Print to Adobe PDF
    - Name as above and put into Folder P-YR-####
    - Once the PDF is created → use the Find tool (magnifying glass) to search the document for the word "test" and just double check the Fate and Ecotox sections have been corrected as per above findings.
    - If no inappropriate "test" is found and the Ecotox hazard attribution is correct, close file and add "_checked" to the file name

f. P-YR-####_ENG Report

- Under IR Report Tab: select View/Edit Engineering Report
    - check it is marked "Complete" (middle of screen after **Engineering Report:**)
        - If not → inform EPA and **STOP**
        - If so, Print (blue button on Right) → PDF Print → Print to Adobe PDF {this is supposed to print the LATEST version}
    - Name as above and put into Folder P-YR-####
- Once the PDF is created → use the Find tool (magnifying glass) to search the document for the word "test"
    - If "test" is found → **STOP** and inform EPA
    - If "test" is not found, close file and add "_checked" to the file name
    -

g. P-YR-####_EXP Report

- Under IR Report Tab: select View/Edit Exposure Report
  - check it is marked "Complete" (middle of screen after **Exposure Report:**)
    - If not → inform EPA and **STOP**
    - If so, Select P-YR-####.exp.doc (under Attachments/Comments/Telephone Log) → Save As PDF
  - Name as above and put into Folder P-YR-####
- Once the PDF is created → use the Find tool (magnifying glass) to search the document for the word "test"
  - If "test" is found → **STOP** and inform EPA
  - If "test" is not found, close file and add "_checked" to the file name

h. P-YR-####_HLTH Report_POST-FOCUS FINAL

- Under Document Tab: Sort **Updated Date** from NEWEST to OLDEST
- Locate **Focus Health Assessment** or **RAD Risk Assessment** or **???**
- Check **Status**: If **NOT** "Complete" → Inform EPA
- Navigate to **Download**, then **Attachments** → click on attachments to reveal all files → click to open most recent {Note: if there are data/study review in addition to the Health assessment, you will need to also open and pdf those too}
- OPEN when prompted → file will Open in WORD
- Perform 'Editorial' and/or QC task as per previous instruction from EPA on this file and re-upload
- Inform EPA that editorial and QC review has been performed

Deliverables for 5.2

(1) EPA and SRC will determine the schedule for the subsequent meetings, as needed.
(2) Meeting materials--list of questions to guide discussion, recommendations on how to structure the pilot, list of SRC staff names that will need to access the OECD QSAR toolbox—due one day before the meeting
(3) Summary of meeting discussion and action items, preferably no later than a day after conducting the EPA-SRC meeting.
(4) SRC will provide materials to EPA on a similar plan and schedule for future meetings. SRC should track the action items and implementation schedule of changes.
Prior to any and all meetings, EPA's TOCOR and/or Keith Salazar) and SRC will discuss the agenda and the goals for the meeting. SRC will circulate the agenda and any other materials preferably one day before the meeting.
(5) Please provide names of selected SRC assessors that will be attending the pre-SAT and pre-FOCUS meetings.
(6) Names of SRC assessors that will write hazard narratives.
(7) Attendance at pre-SAT, SAT, pre-FOCUS and FOCUS meetings, as well as follow-up emails to EPA Technical Contact to clarify any identified issues—due the same day after attending the meetings.
(8) Commence support for Development of draft Part B documents
(9) Draft Part As and Part Bs-- EPA will negotiate timeline with SRC after SRC staff receives training.
(10) Commence support for revisions to Part A/Part B documents based on OPPT reviewers (e.g., OPPT IO reviewers).

Deliverables for 5.3

(1) Draft human health narratives—EPA will negotiate timeline with SRC after SRC staff receives training.

Deliverables for 5.4

(1) Draft report addressing post-FOCUS HH work—EPA will negotiate timeline with SRC.

Deliverables for 5.5

(1) Summary of generic name reviews and findings relevant to the 4 outlined parts above—EPA will negotiate timeline with SRC after SRC staff receives training.

Deliverables for 5.6

(2) Edited human health risk assessments and/or SAT reports for back log cases—EPA will negotiate timeline with SRC after SRC staff receives training.

5.6.1 Checklist for reviewing Post-FOCUS cases

1. Check all spelling
2. Check for scientific accuracy (e.g. doses and concentrations are presented properly as mg/kg-day, mg/m^3)
3. Human Health Summary
    a. (if necessary) Delete last sentence in the first paragraph stating that "EPA concludes there is low/moderate/high/ concern for human health hazard for the chemical substance.
    b. (if necessary) Delete last one or two sentences stating: "The risk estimates for this chemical are for the intended conditions of use. Other conditions of use and their risks were not evaluated."
4. Hazard Summary
    a. Check that the health effects identified in the SAT Health Summary are accurately represented in the Hazard summary (1.1)
    b. Delete the word "uncertain" if the concern identified is written as "uncertain concerns for …"
5. Risk Summary
    a. Check that all health effects identified in the Hazard Summary are discussed in the Risk Summary. If a health concern is mentioned, then the Risk Summary should explicitly state if the hazard is either a risk or not.
    b. Delete the word "potential" if the phrase "potential risks were identified"
    c. For worker risks that are qualitatively evaluated, use and modify the text below as necessary to characterize the risk:
        i. Risks for irritation (and/or sensitization) for workers via dermal (and/or inhalation) exposure cannot be quantified due to lack of dose-response information for this(these) hazard (s). However, exposures can be controlled by the appropriate use of personal protective equipment's (PPE), such as impervious gloves (and/or eye protection and/or respiratory protection). EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the submitter, in a manner adequate to protect them. Therefore, EPA does not expect risk for the irritation (and/or sensitization) endpoint.
    d. Ensure that the correct MOE and benchmark are presented in the Risk Summary as in the Risk Calculation section.
    e. If Consumer risks were not assessed due to no expected uses, use the phrase:
        i. Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.
6. Potentially Useful Information
    a. If the assessment uses an older template with "recommended testing", edit the form to match the current template.
    b. Use the PUI translator located on the RAD share drive to convert recommended testing to "PUI" language

7. SAT Summary
    a. Delete "PMN Health Rating" section
    b. Delete "SAT Key Words" section
    c. Ensure that all sections are filled in. If no information is available, then note as necessary. For example, if PMN data was not provided then state "No data available" in PMN Data section
    d. Check and edit the Chemical Category entry with EPA's 2010 Chemical Category document for accuracy.
8. Human Health Risk (Part B)
    a. Check NCR for the latest engineering and exposure reports and ensure that the health report accurately states the most recent worker and general population and consumer exposures.
    b. Check the engineering report for the phrase "testing desired" for human health or ecotoxicity, and if necessary, contact the engineering representative to remove the phrase.
    c. Check all calculations for accuracy. For dermal calculations, check that absorption was correctly adjusted for.

5.7 Collect EPA Human Health Recommendations

The Risk Assessment Division is requesting SRC's support to the New Chemicals Program and the Task below outlines the roles and responsibilities of the contractors.

EPA's Office of Pollution Prevention and Toxics is working on risk management activities for new chemical substances.

Step 1

SRC is tasked to extract information from NCR and populate columns H, I, J and K in the attached spreadsheet. You may want to reformat the spreadsheet to provide information in separate rows.

- Column H: These are the hazards identified at the SAT meeting. Please go to the SAT report to extract hazards and list them in separate rows.
- Column I: These are the hazards identified in the FOCUS reports (Part A/Part B reports). These reports are generally available in NCR in the Documents tab and appear as Word documents.
- Columns J and K: These are recommendations on personnel protective equipment (PPE) for gloves and respirators. This information is available in different sources, but generally FOCUS briefings contain this information. These documents are typically found in NCR in the Documents tab.

The content of the table will contain CBI information and should be saved on the CBI LAN side in the folder G://Human Health- New Chemicals/Crosswalk_2018

5.8 Consolidate EPA Information on Commonly Used Analogs

EPA staff have developed multiple approaches for collecting human health toxicity data on commonly used analogs. Currently, this information resides in a number of separate files on the CBI LAN. The purpose of this technical direction is to have SRC consolidate currently held information on these chemicals into one file, which will help us determine next steps, which may include resolving conflicts, adding to AIM and/or building out this database. Note that this new resource is not expected to contain CBI data, but since the source folders are held there, the consolidated file will reside on the CBI LAN.

EPA created a folder on the CBI LAN (J:\For SRC\TD4 HH analog data) and placed all current source documents containing data for analogs of interest in there, including:

- Frequently Encountered Analog Substances (Excel) Abbreviate: **FEAS**
- RfC-RfD-NOAELs-LOAELs-PODs-etc (Excel) Abbreviate: **RFC**
- SAT & FOCUS working chemical categories (Word) Abbreviate **S&F**

Using these files, SRC will:

1. Extract chemical-specific information for each chemical included in each document provided and enter it into the excel spreadsheet provided with this TD, and saved to the J drive in the folder above, titled "Commonly Used Analogs for Scoping".
    - For chemicals in S&F documents, do not look up values as directed in the document, at this time we are only interested in vales that are readily at hand.
    - In addition, if there is any other information missing or data gaps (e.g., study data, doses, references) SRC is not tasked with searching for this information at this time.
    - At this time PODs are sufficient, and we do not need to track MOEs, MCLs or any other reference value.
2. If there are conflicting values enter the values in separate lines. Highlight all values found for a single chemical (in yellow or some other color) so we can readily identify such conflicts.
3. Please fill in any missing CAS RN and add the SMILES notation (if applicable).
4. For the file source column, please use the abbreviations noted above. This will help us resolve conflicts.
5. Note that study summaries are much longer in the S&F Word document. Please extract from these summaries only basic study type information, e.g., 90 day inhalation study, or OECD 422 (depending on what is provided in the source document), and summarize results in a couple of words, e.g., liver effects (increased weight, vacuolization, increased liver enzymes).

C. REPORTING REQUIREMENTS AND SCHEDULE OF BENCHMARKS & DELIVERABLES:

As described in Task 2 and in the invoice instructions, the Contractor shall provide a monthly report CO, COR and TOCOR which identifies project staff and all activities and milestones associated with the Task Order assignments planned and in progress. The monthly report in progress tasks shall be included in the monthly reports which will be referenced when the Voucher Validation review is performed monthly at the end of each billing cycle.

As per the Task Order or request for a proposal, the Contractor shall provide the Agency with a proposal within the timeframe specified for this Task Order. The EPA CO, TOCORs, or panel members will review the proposal and provide the Contractor with an approval or disapproval, and revision (if necessary) in writing. The timelines involved, will proceed as stipulated in the request for a proposal or Contract.

The Contractor shall prepare a Quality Assurance Project Plan for this Task Order. EPA Requirements for Quality Assurance Project Plans (QA/R-5).

For most deliverables, the EPA TOCOR will assign a tentative due dates and instructions when work is routed to the Contractor. If within three business days, the Contractor expresses no concern regarding the due date; the date shall be deemed settled by tacit agreement.

SPECIFIC SCHEDULE OF DELIVERABLES:

Tasks	Deliverables	Schedule
Task 1:	Project Management and QAPP	QAPP within ten days of task order award
Task 2:	Monthly progress reports	Monthly reports
Task 3:	Developing reports for Assessing New Chemicals	Products shall be submitted within the same day as the contractor is tasked with the work.
Task 4:	Model Maintenance	Products shall be submitted based on technical direction issued by the TOCOR.
Task 5:	Supplemental Support on PMN Human Health Hazard Assessment	Products shall be submitted based on technical direction issued by the TOCOR.

E. DELIVERABLES

For each deliverable submitted electronically, the contractor shall submit electronic copies to EPA in a format that EPA can support. Deliverables shall be submitted through electronic mail, or through another method determined mutually acceptable by the contractor and EPA.

F. ACCEPTABLE QUALITY LEVEL FOR TASKS

See Attachment: Quality Assurance Surveillance Plan

Performance Criteria Analysis – TASKS		
Performance Indicator	**Standard**	**Acceptable Quality Level (AQL)**
Timely submission of report	Reports submitted within time frame pre-negotiated with Task Order COR	95%

Free of substantive technical, guideline, or format errors	Reports submitted with zero substantive errors including but not limited to discrepancies, omissions, inaccuracies, and/or inappropriate data evaluation	95%

F.1 Method of surveillance

Final deliverables prepared by the contractor undergo a secondary review process in OPPT. Each report has a designated EPA reviewer. The EPA reviewer conducts a review of the contractor's deliverable. The EPA reviewer will provide feedback to the TOCOR to send back to the contractor should revisions be needed. The TOCORs will compare agency due dates or approved revised due dates to completed date of reports, quarterly and calculate the percentage of late reports. See attached QASP.

F.2 Period of Performance

The period of performance of this task order is:

Base: 12 months from award date
Option 1: 12 months from option exercise
Option 2: 12 months from option exercise
Option 3: 12 months from option exercise
Option 4: 12 months from option exercise

G. TASK ORDER TYPE

Time and materials

H. INSPECTION AND ACCEPTANCE

H.1 Quality Assurance Project Plan

The contractor shall submit the following quality system documentation to the CO at the time frames identified below:

	Documentation	Specifications	Due
X	Quality Assurance Project Plan for the Task Order	EPA Requirements for Quality Assurance Project Plans (QA/R-5)	Within 15 days of Task Order Award

This documentation can be found on the following EPA website – https://www.epa.gov/quality/epa-qar-5-epa-requirements-quality-assurance-project-plans

This documentation will be prepared in accordance with the specifications identified above or equivalent specifications defined by EPA.

The Government will review and return the quality documentation, with comments, and indicating approval or disapproval. If necessary, the contractor shall revise the documentation to address all comments and shall submit the revised documentation to the government for approval.

The contractor shall not commence work involving environmental data generation or use until the Government has approved the quality documentation.

I. TASK ORDER ADMINISTRATION DATA

I.1 Contract Administration Representatives

Contracting Officer: Genine McElroy, McElroy.Genine@epa.gov

Contract Level Contracting Officer's Representative: Brian Lobar, lobar.brian@epa.gov

Task Order Contracting Officer's Representative (TOCOR): Clifton Townsend, Townsend.clifton@epa.gov

Alternate TOCOR: Kara Koehrn, Koehrn.kara@epa.gov

J. INVOICING

Invoices shall be submitted in accordance with contract clause G.3 EPAAR 1552.232-70 SUBMISSION OF INVOICES. (JUN 1996) - ALTERNATE I (JUN 1996).

(End of Clause)

K. TASK ORDER CLAUSES

FAR 52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the contractor within 5 calendar days before the expiration of this contract; provided that the Government gives the contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 60 Months. (End of clause)

LOCAL CLAUSE - EPA-B-32-103A - LIMITATION OF GOVERNMENT'S OBLIGATION

(a) Severable services may be incrementally funded. Non-severable services shall not be incrementally funded. Contract line items ___**1**__ through __**5**___ are severable and may be incrementally funded. For these items, the sum of $225,000.00 of the total price is presently available for payment and allotted to this contract.

(b) For items identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including reimbursement in the event of termination of those items for the Government's convenience, approximates the total amount currently allotted for those items to the contract. The Contractor shall not continue work on those items beyond that point. Subject to the clause entitled, "Termination for Convenience of the Government," the Government will not be obligated, under any circumstances, to reimburse the Contractor in excess of the amount payable by the Government in the event of the termination of applicable contract line items for convenience including costs, profit, and estimated termination costs for those line items.

(c) Notwithstanding the dates specified in the allotment schedule in paragraph (h) of this clause, the Contractor will notify the Contracting Officer, in writing, at least 5 days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85% of the total amount currently allotted to the contract for performance of the applicable items. The notification will state (1) the estimated date when that point will be reached and (2) an estimate of additional funding, if any, needed to continue performance of the applicable line items up to the next scheduled date for the allotment of funds identified in paragraph (a) of this clause, or to a substitute date as determined by the Government pursuant to paragraph (d) of this clause. If, after such notification, additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the clause entitled "Termination for Convenience of the Government."

(d) The parties contemplate that, subject to the availability of appropriations, the Government may allot additional funds for continued performance of the contract line items identified in paragraph (a) of this clause and will determine the estimated period of contract performance which will be covered by the funds. If additional funds are allotted, the Contracting Officer will notify the Contractor in writing. The Contractor shall not resume performance of the contract line items identified in paragraph (a) until the written notice is received. The provisions of paragraphs (b) through (d) of this clause will apply in like manner to the additional allotted funds and to the new estimated period of contract performance. The contract will be modified accordingly.

(e) The Government may, at any time prior to termination, allot additional funds for the performance of the contract line items identified in paragraph (a) of this clause.

(f) The termination provisions of this clause do not limit the rights of the Government under the clause entitled "Default". The provisions of this clause are limited to the work and allotment of funds for the contract line items set forth in paragraph (a) of this clause. This clause no longer applies once the contract is fully funded.

(g) Nothing in this clause affects the right of the Government to otherwise terminate this contract pursuant to the contract clause entitled "Termination for Convenience of the Government".

(h) The parties contemplate that the Government may obligate funds to this contract in accordance with the following schedule:

RECAPITULATION:

	PRIOR AMOUNT	THIS MOD.	NEW AMOUNT
BASE PERIOD			
Total Maximum Amount:	$0.00	$0.00	$1,918,220.00
Funded Amount:	$0.00	$0.00	$225,000.00

(End of clause)

L-1 EPA-J-52-101 LIST OF ATTACHMENTS

ATTACHMENT 1: QUALITY ASSURANCE SURVEILLANCE PLAN

ATTACHMENT 1

QUALITY ASSURANCE SURVEILLANCE PLAN

PERFORMANCE REQUIREMENT	PERFORMANCE MEASURE (PM)	PERFORMANCE STANDARD	SURVEILLANCE METHOD	INCENTIVES & DISINCENTIVES
MANAGEMENT AND COMMUNICATION: The contractor shall maintain contact with the EPA CO, COR, and TOCOR throughout the performance of the contract.	Contractor shall immediately bring potential problems to the appropriate EPA personnel and shall recommend actions that would mitigate or resolve the problem.	Issues that impact project schedules and costs shall be brought to the attention of the EPA within 3-days of occurrence.	All active task orders will be reviewed by the EPA to identify unreported issues.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Business Relations in the Contractor Performance Assessment Reporting System (CPARS).
TIMELINESS: For every Task Order awarded establishing a firm, specific delivery date for the generation of a report, the contractor shall deliver such report to the COR, TOCOR and CO no later than the time specified in the order's PWS.	Deliverables and related work must comply with contractual timeliness requirements. The contractor will be evaluated on its responsiveness to all task orders.	95% of all deliverables and related work shall be completed on time within task schedule and/or tech. direction requirements.	100% inspection of all deliverables and related work by the TOCOR; TOCOR will document the timeliness of all work requirements.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation of Timeliness in the Contractor Performance Assessment Reporting System (CPARS).
TECHNICAL QUALITY: For every task order awarded, the analyses conducted by the contractor shall be factual, defensible, credible, and based on sound scientific methods. All data shall be collected from reputable sources and quality assurance measures shall be conducted in accordance with the agency requirements outlined in the task orders.	All deliverables and related work must be complete, accurate, thorough, and professionally credible.	Data are 100% accurate; review demonstrates a high level of expertise and credibility with regard to personnel and use of scientific methodology. Task Orders shall be conducted in strict conformance with approved QA plans. Outputs shall withstand internal review by the US EPA and outside scientific reviewers.	EPA Staff will conduct secondary reviews of work completed by the contractor. Feedback will be provided.	Performance will be considered in the award of subsequent task orders and will be factored into the annual evaluation in the category of Quality of Product or Service in the Contractor Performance Assessment Reporting System (CPARS).